Regulations are to chapter I of title 21 unless otherwise noted.

[45 FR 7484, Feb. 1, 1980, as amended at 45 FR 23686, Apr. 8, 1980; 57 FR 58404, Dec. 10, 1992]

§ 861.5 Statement of policy.

In carrying out its duties under this section, the Food and Drug Administration will, to the maximum extent practical:

(a) Use personnel, facilities, and other technical support available in other Federal agencies;

(b) Consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard-setting entities; and

(c) Invite participation, through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution.

§ 861.7 Contents of standards.

Any performance standard established under this part will include such provisions as the Food and Drug Administration determines are necessary to provide reasonable assurance of the safety and effectiveness of the device or devices for which it is established. Where necessary to provide such assurance, a standard will address (but need not be limited to):

(a) Performance characteristics of the device;

(b) The design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems;

(c) The manufacturing processes and quality control procedures applicable to the device;

(d) Testing of the device on either a sample or a 100-percent basis by the manufacturer, or, if it is determined that no other more practical means are available to the Food and Drug Administration to assure the conformity of the device to the standard, providing for testing by the Food and Drug Administration or a third person to ensure that the device conforms to the standard;

(e) The publication of the results of each test or of certain tests of the device to show that the device conforms to the portions of the standard for which the test or tests were required;

(f) Manufacturers' certification to purchasers or to the Food and Drug Administration that the device conforms to the applicable performance standard;

(g) Restrictions on the sale and distribution of the device, but only to the extent authorized under section 520(e) of the act;

(h) The use, and the form and content, of labeling for the proper installation, maintenance, operation, and use of the device. Among the provisions that may be required in the labeling are warnings; storage and transportation information; expiration dates; the date and place of manufacture; the results that may be expected if the device is used properly; the ranges of accuracy of diagnostic information; instructions regarding the proper care of, and the proper components, accessories, or other equipment to be used with the device; and statements concerning the appropriate patient population, for example, a statement that the device is considered safe and effective only when used by, or in the treatment of, a patient who has been tested by particular designated procedures and found to have an illness or condition for which use of the device is indicated by a person skilled in the use of the device.

Subpart B—Procedures for Performance Standards Development and Publication

§ 861.20 Summary of standards development process.

The procedure by which a performance standard for a device may be established, amended, or revoked is as follows:

(a) The Food and Drug Administration (FDA) will publish in the FEDERAL REGISTER a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(1) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device will:

(i) Set forth a finding, with supporting justification, that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device;

(ii) Set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate;

(iii) Invite interested persons to submit to the Food and Drug Administration, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to § 860.132 of this chapter, based on new information relevant to the classification; and

(iv) Invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Commissioner of Food and Drugs.

(2) A notice of proposed rulemaking for the revocation of a performance standard will set forth a finding, with supporting justification, that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(b) A notice under this section will provide for a comment period of not less than 60 days.

(c) If, after publication of a notice under paragraph (a) of this section, FDA receives a request to change the classification of the device, FDA will, within 60 days of the publication of the notice and after consultation with the appropriate panel under § 860.125 of this chapter, either deny the request or give notice of its intent to initiate a change in the classification under § 860.130.

(d) If FDA initiates a rulemaking proceeding under paragraph (a) of this section, FDA will:

(1) Complete the proceeding and establish the performance standard for the device in accordance with this part and § 10.40 of this chapter; or

(2) Terminate the proceeding by publishing in the FEDERAL REGISTER a notice announcing such termination and the reasons therefor and, unless the proceeding is terminated because the device is a banned device, initiate a proceeding in accordance with section 513(e) of the act to reclassify the device; or

(3) Take other appropriate action.

[57 FR 58404, Dec. 10, 1992]

§ 861.24 Existing standard as a proposed standard.

(a) The Food and Drug Administration may accept an existing standard or a proposed or draft standard if it includes:

(1) A description of the procedures used to develop the standard and a list of the persons and organizations that participated in its development, to the extent that such information is available or reasonably obtainable;

(2) An identification of the specific portions of the existing standard that the person submitting the standard believes are appropriate for adoption as, or inclusion in, the proposed standard; and

(3) A summary of the test data, or, if requested by the Food and Drug Administration, all such data or other information supporting the specific portions of the standard identified by the person submitting the standard.

(b) The Food and Drug Administration will publish a notice in the FEDERAL REGISTER stating either that it has accepted, or accepted with modification, as a proposed standard, an existing standard or one that has been developed, or that an existing standard is not acceptable, together with the reasons therefor.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§ 861.30 Development of standards.

The Food and Drug Administration (FDA), while engaged in the development of a proposed standard under this section will:

(a) Support its proposed performance standard by such test data or other documents or materials as may reasonably be required;

(b) Provide interested persons an opportunity to participate in the development of the standard by accepting comments and, where appropriate, holding public meetings on issues relating to development of the standard.